REMARKS

This paper is responsive to the Office Action mailed February 11, 2008. All claims 1-4, 7-14, 16-24 and 29-32 were finally rejected in the Office Action.

Section 102(e) rejections.

Claims 1, 2, 7-10, 14, 16-18, 21-24, 29 and 30 were rejected under 35 U.S.C. §102(e) as being anticipated by Osypka et al (US 2003/0216771). For the following reasons, Applicants respectfully request reconsideration of these rejections.

The present invention is directed to a percutaneous entry system, and more particularly, to an insertion system for substantially bloodless percutaneous entry into a body vessel. As stated in the Background section of the present application, when medical percutaneous entry systems were originally developed, a clinician would typically insert a needle through the skin and into a body vessel, such as an artery. Visual proof that the needle tip was in the correct location was obtained when a "squirt" of blood shot out of the needle hub. As concern arose in subsequent years about the dangers of blood borne pathogens, health regulations were implemented to restrict exposure of the medical workers to blood. As a result, many devices were developed to seek substantially bloodless entry, and thereby limit the exposure of medical personnel to blood and other body fluids. The present device represents an advancement of this technology, wherein the device enables substantially bloodless entry not only upon initial entry of the needle into the artery or vein, but also during the subsequent insertion of other apparatus, such as a wire guide straightener or a dilator. In addition, the technician is able to confirm that proper entry has been made.

Claims 1, 2, 7-10, 14 and 16.

Claim 1 of the application is directed to a percutaneous insertion system. The insertion system comprises a needle assembly, a needle hub attachment assembly, and an assembly comprising a hemostatic segment. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end of the needle assembly comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom, and the proximal end comprises a needle hub. The needle hub attachment assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end of the needle hub attachment assembly is sized and configured for leak-free engagement with the needle hub. The needle hub attachment assembly includes a chamber communicating with the needle assembly for receiving withdrawn body fluid. The assembly comprising a hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly and having an opening permitting passage of a wire guide therethrough. The distal end is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The passageway is aligned with the needle assembly passageway and needle hub attachment assembly passageway to form a path for insertion of the wire guide into the body vessel. The distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

The Osypka patent publication describes a much different type of device, namely a vascular introducer assembly 10. Vascular introducer assemblies of this type are utilized for introducing a medical instrument therethrough, such as a pacemaker lead or a catheter. The Osypka device is not a percutaneous insertion

system within the meaning of the present claims, and is not capable of functioning as such in a substantially leak-free manner as described.

The device disclosed in Osypka comprises an introducer assembly that includes a dilator 28, an introducer sheath 18 for accommodating the dilator, a locking mechanism 24 for temporarily securing the dilator and the sheath to one another, and a trocar seal 58 for limiting egress of fluid. According to the patent publication, the dilator is inserted into a vessel over a guidewire 86 that has previously been inserted into the vessel. The guidewire is inserted in conventional fashion, e.g., through the bore of a needle that has previously been percutaneously inserted. Following insertion of the guidewire, *the needle is withdrawn,* and the introducer assembly cited by the Examiner is thereafter introduced over the guidewire in well-known fashion. See, e.g., paragraphs [0006] and [0049] of Osypka. (Paragraph [0006] is reprinted below.) Those skilled in the art will appreciate that the needle described in Osypka for initial insertion bears more similarities in structure and function to the presently claimed percutaneous insertion system than does the introducer assembly cited by the Examiner as the basis of the rejections.

The Examiner has identified certain structure in Osypka that is said to meet the limitations of the claimed insertion system. As understood by Applicants, the Examiner (at page 2 of the Office Action) contends that introducer sheath 18 meets the limitation of a needle, introducer engagement hub 20 meets the limitation of a needle hub, sealing cap 22 meets the limitation of a needle hub attachment assembly, and dilator 28 meets the limitation of a hemostatic segment.

Applicants respectfully submit that the claimed percutaneous insertion system of claim 1 is quite different from the introducer assembly disclosed in Osypka. For example, the system of claim 1 includes a needle assembly as

described above, the distal end of which comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The Examiner cites a conventional introducer sheath 18 as meeting this limitation. However, the introducer sheath in Osypka is not structured for percutaneous entry into a vessel for withdrawing a body fluid. Rather, as Osypka points out (paragraph [0049]), the introducer assembly is inserted over a guidewire "as shown in FIG. 5 and as described in the above background." According to the Background,

> [0006] Typically, the percutaneous introduction of an introducer assembly is accomplished by first inserting a needle into the blood vessel at a desired location and its position is verified by observing fluid return or by a similar method. While the needle is held firmly in place, a guidewire is inserted through the needle cannula to the desired depth. The guidewire is then held in place and the needle is withdrawn. Pressure is applied on the puncture site in order to minimize blood loss. Next, the introducer assembly is threaded over the guide wire. The introducer assembly is grasped close to the skin surface and advanced through the tissue to the desired position. Then, the dilator and guidewire are removed, leaving the sheath installed. A lead, catheter or similar diagnostic or therapeutic device is then introduced into the sheath and advanced to the desired position. ...

Thus, it is clear that the introducer sheath identified by the Examiner in Osypka does not meet the limitation of a needle. In fact, it was even recognized and stated by Osypka that it is still necessary to utilize a needle in order to properly place the Osypka introducer assembly. If the introducer sheath truly met the limitation of the needle, there would have been no reason to separately use a needle as taught in Osypka. Clearly, Osypka knew better. Reconsideration on this basis is respectfully requested.

Furthermore, it should be noted that the principles of law relating to anticipation are clear. "A claim is anticipated only if each and every element as

set forth in the claim is found, expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). Analysis of whether a claim is patentable over the prior art under 35 U.S.C. § 102 begins with a determination of the scope of the claim. The scope of the claim in a patent application is determined not solely on the basis of the claim language, but upon giving the claim its broadest reasonable construction in light of the specification *as would be interpreted by one of ordinary skill in the art. In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004) (emphasis added). See also, *Ex parte Mary Smith*, Appeal No. 2007-1925, Board of Patent Appeals and Interferences, June 25, 2007, pages 6-7.

One skilled in the art would clearly not consider the introducer sheath of Osypka as a needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom, and in fact, even Osypka did not make such a connection. Rather, Osypka properly emphasized that a needle must still be used to position the guidewire, prior to introduction of the sheath. Introducer sheaths and needles have separate functions in the medical arts. One skilled in the art would not consider such devices to be interchangeable, or consider that the identification of one such device in a reference somehow teaches the structure of the other.

Osypka also does not include an assembly comprising a hemostatic segment as claimed. As further stated in claim 1, this assembly has a proximal end, a distal end, and a passageway extending therebetween. The hemostatic segment comprises a valve positioned in the passageway at the proximal end of the assembly and has an opening permitting passage of a wire guide therethrough. The distal end is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The passageway is aligned with the needle assembly passageway and needle hub attachment assembly passageway to

form a path for insertion of the wire guide into the body vessel. The distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

The Examiner has identified dilator 28 of Osypka as meeting the limitation of the assembly comprising a hemostatic segment. Applicants respectfully point out that dilator 28 is very different from the recited element, both structurally and functionally. One skilled in the art recognizes that a dilator, such as the dilator of Osypka, is provided to controllably stretch the opening formed by the needle to a size such that the introducer sheath can be percutaneously introduced into the body opening. One skilled in the art would not equate the assembly claiming a hemostatic segment as claimed herein with a conventional dilator.

In addition to the foregoing, Applicants respectfully point out that the valve in the claimed assembly comprising a hemostatic segment is positioned in the passageway at the *proximal end* of the hemostatic assembly. A preferred embodiment of this valve is illustrated in Figs. 1 and 2 of the present application as reference element "44". No such valve is noted *in the passageway* at the proximal end of the dilator 28. The Examiner has specifically identified two valves (58, 80) in Osypka, but neither of these valves is positioned in the passageway of an assembly comprising a hemostatic segment (i.e., the dilator according to the Examiner's interpretation). If the Examiner persists in this rejection, she is respectfully requested to specifically provide additional explanation of how this claimed structure is met by Osypka, so that this construction can be properly addressed by Applicants.

Still further, according to the language of claim 1, the *distal end* of the assembly comprising a hemostatic segment is sized and configured for leak-free engagement with the proximal end of the needle hub attachment assembly. The distal end of the dilator 28 in Osypka (asserted by the Examiner as the element

that meets the limitation of the assembly comprising a hemostatic segment) extends into the body vessel (Fig. 5), and is the distalmost feature of the introducer assembly. It is clearly not sized and configured for leak-free engagement with the *proximal end* of the needle hub attachment assembly.

Furthermore, the distal end of the assembly comprising a hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. This is best shown in Fig. 5 of the present application, wherein distal end 42 tapers to endhole 43. According to the application:

> The tapered end of the inserter is sized such that it can be snugly inserted into the proximal end of the needle hub attachment assembly 20. Endhole 43 has a diameter that substantially matches the diameter of the wire guide to inhibit blood reflux through the device. However, the diameter of endhole 43 may be formed to be slightly larger than that of the wire guide to permit smooth insertion and/or extraction of the wire guide from the inventive system 10. Page 8, lines 18-23.

There is no teaching or suggestion in Osypka of this diametrical relationship between the dilator and a wire guide. The Examiner has identified Fig. 5 in Osypka as meeting this limitation, however upon review of this figure, Applicants dispute that it teaches a hemostatic segment that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide. Rather, Fig. 5 merely appears to show a wire guide passing through a dilator. Further, Applicants respectfully submit that nothing in the specification of Osypka provides support for the Examiner's findings in this regard. This discussion is essentially moot in any event, since the *distal end* of the assembly comprising a hemostatic segment (i.e., the dilator 28 in Osypka) is not sized and configured for leak-free engagement with the *proximal end* of the needle hub attachment assembly for the reasons specified above. Simply put, Applicants

submit that one skilled in the art would not read and interpret the structure of Osypka in the manner in which it has been cited herein.

Finally, according to claim 1, the passageway of the assembly having a hemostatic segment is aligned with the needle assembly passageway and needle hub attachment assembly passageway to form a path for insertion of the wire guide into the body vessel. In the Osypka device, the passageway through the dilator comprises the entire path for insertion of the wire guide. It is not aligned with the other passageways to form a path for insertion of a wire guide as claimed. Once again, Applicants respectfully assert that one skilled in the art would not interpret this structure in the manner in which it has been cited herein. Reconsideration is respectfully requested.

Thus, for at least the foregoing reasons, claim 1 of the present application is not anticipated by the Osypka publication. Claims 2, 7-10, 14, 16 and 29 depend, directly or indirectly, from claim 1. Accordingly, these claims are not anticipated for at least the same reasons that claim 1 is not anticipated.

In addition to the forgoing, Applicants respectfully refer to the limitations of claim 10. According to claim 10, the tapering distal end of the assembly comprising a hemostatic segment is received in the elastomeric valve of the needle hub attachment assembly. Applicants are unsure how the Examiner has construed Osypka to meet this limitation, as it clearly does not appear to be met. Further explanation of the grounds for this rejection is also respectfully requested, so that the rejection can be properly addressed in subsequent prosecution or appeal.

Claims 17, 18 and 21-24.

Independent claim 17 is also directed to a percutaneous insertion system. The insertion system of claim 17 includes a needle assembly having a first

hemostatic segment, and an assembly comprising a second hemostatic assembly. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The assembly comprising a second hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The *distal end* is sized and configured for leak-free engagement with the *proximal end* of the needle assembly. The passageway is aligned with the passageway of the needle assembly to form a path for insertion of a wire guide into the body vessel. The second hemostatic segment comprises a valve positioned *in the passageway* at the proximal end of the assembly, and having an opening permitting passage of the wire guide therethrough. The distal end of the assembly comprising a second hemostatic segment tapers to an endhole having a diameter substantially the same as the diameter of the wire guide.

As stated above, Osypka does not teach an elongated needle for percutaneous entry, a distal end of the assembly that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide, or respective segments having passageways aligned to form a path for insertion of a wire guide. Further, Osypka does not teach an arrangement wherein a *distal end* of an assembly comprising a second hemostatic segment is sized and configured for leak-free engagement with a *proximal end* of a needle assembly. Additionally, Osypka does not teach a first hemostatic segment as part of a needle assembly, nor does it teach a valve positioned in the passageway of the proximal end of the assembly. Thus, for at least the foregoing reasons, claim 17 of the present application is not anticipated by the Osypka publication. Claims 18 and 21-24 depend, directly or indirectly, from claim 17. Accordingly, these claims are not anticipated for at least the same reasons that claim 17 is not anticipated.

Claim 30.

Independent claim 30 is also directed to a percutaneous insertion system. The insertion system comprises a needle assembly and an assembly comprising a hemostatic segment. The needle assembly has a proximal end, a distal end, and a passageway extending therebetween. The distal end comprises an elongated needle for percutaneous entry into a body vessel for withdrawing a body fluid therefrom. The assembly comprising a hemostatic segment has a proximal end, a distal end, and a passageway extending therebetween. The *distal end* is sized and configured for leak-free engagement with the *proximal end* of the needle assembly. The passageway is aligned with the needle assembly passageway to form a path for insertion of a wire guide into the body vessel. The hemostatic segment comprises a valve positioned *in the passageway* at the proximal end of the assembly. The valve tapers in a distal direction to an endhole having a diameter substantially the same as the diameter of the wire guide.

As stated above, Osypka does not teach an elongated needle for percutaneous entry, a distal end of the assembly that tapers to an endhole having a diameter substantially the same as the diameter of the wire guide, or respective segments having passageways aligned to form a path for insertion of a wire guide. Further, Osypka does not teach an arrangement wherein a *distal end* of an assembly comprising a hemostatic segment is sized and configured for leak-free engagement with a *proximal end* of a needle assembly. In addition, Osypka does not teach a valve positioned in the passageway of the proximal end of the assembly. Thus, for at least the foregoing reasons, claim 30 of the present application is also not anticipated by the Osypka publication.

Sec. 103(a) rejections.

Claims 3, 4, 12, 19 and 32.

Claims 3, 4, 12, 19 and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka in view of Raulerson (USP 6,551,281). Raulerson was cited for teaching a guidewire advancer comprising a guidewire holder that is preloaded with a guidewire fastened in a loop so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient. Claims 3, 4 and 12 depend from claim 1, and therefore include all of its limitations, including the limitations relating to the needle assembly, needle hub attachment assembly, and assembly comprising a hemostatic segment, as described in greater detail hereinabove. These limitations are neither taught nor suggested in Raulerson. Claim 19 depends from independent claim 17, and claim 32 depends from independent claim 30. These claims include all of the limitations of the respective independent claim, including the limitations relating to the needle assembly and the assembly comprising a hemostatic segment, as described above. Thus, claims 3, 4, 12, 19 and 32 are not obvious in view of the cited combination.

Claims 11, 20, 31.

Claims 11, 20 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka in view of Padilla et al (USP 5,984,895). Padilla was cited for teaching a vascular blood flashback containment device that is transparent to allow for the visualization of blood. Claim 11 depends from claim 1, claim 20 depends from claim 17, and claim 31 depends from claim 30. Therefore, these dependent claims include all of the limitations of the respective independent claims, as recited above. These limitations are neither taught nor

suggested in Padilla. Thus, claims 11, 20 and 31 are not obvious in view of the cited combination.

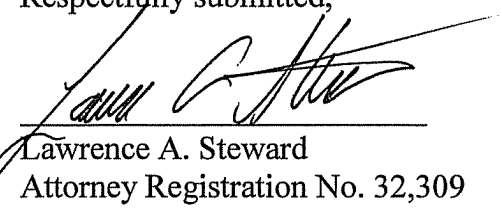
Claim 13.

Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Osypka. Claim 13 depends from claim 1, and includes the additional limitation that at least one of the leak-free engagements comprises a luer lock assembly. Since claim 13 depends from claim 1, it includes all of the limitations of claim 1 as previously described herein. As stated above, Osypka does not teach or suggest such features. Accordingly, claim 13 is not obvious in view of Osypka.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of the claims have been overcome, and that all claims 1-4, 7-14, 16-24 and 29-32 are in condition for allowance. Accordingly, Applicants request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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